

## REMARKS

### The Invention

In general, the present invention features polypeptides consisting of a BAX ART domain. The administration of these polypeptides to a population of cells results in an increase in apoptosis relative to an untreated control population. As a consequence of this activity, the polypeptides are useful for treating conditions of excessive cell growth, such as cancer.

### The Office Action

Examination of claims 1-29 is reported in the present Office Action. Claims 7-9 and 16-29 are drawn to a non-elected invention, were not considered, and are cancelled herewith. Claims 1-6 and 10-15 stand rejected under 35 U.S.C. § 112, second paragraph and claims 3-5 and 11-13 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 1-3, 6, 10, 14-15 are further rejected under 35 U.S.C. § 102(e). Each of these rejections is discussed in detail below.

### Support for Amendments

Amended claims 2 and 4, as well as new claims 35-41, are directed to polypeptides consisting of a BAX ART domain having the sequence of human BAX ART (SEQ ID NO: 3), mouse BAX ART (SEQ ID NO: 4), or rat BAX ART (SEQ ID NO: 5). Support for this amendment is found in Figure 2B of the application. No new matter is added by

the present amendments.

Applicants note that all pending claims, including new claims, read on the elected species of SEQ ID NO: 3.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-6 and 10-14 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In particular, the Examiner contends that recitation of the term “substantially” in claims 1, 10, and dependent claims thereof is open to too great a degree of interpretation. In light of the present amendment to claims 1 and 10, applicants respectfully request that this rejection be withdrawn.

Claim 3 is further rejected based on the Examiner’s assertion that the metes and bounds of the term “decreases apoptosis” cannot be determined. Claim 3 has been cancelled, thus rendering this aspect of the rejection moot.

Claims 4 and 12, which are directed to a “degenerative cell,” are rejected on the basis that recitation of this term is unclear. Claims 4 and 12 have been cancelled and this rejection may now be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 3-5 and 11-13 are rejected for lack of enablement. These claims are now cancelled and this rejection may now be withdrawn.

Rejection under 35 U.S.C. § 102(e)

The Examiner rejects claims 1-3, 6, 10, and 14-15 under 35 U.S.C. § 102(e) as being anticipated by Korsmeyer *et al.* (U.S. Patent 5,691,179, hereinafter “Korsmeyer”). In applying this rejection, the Examiner states that Korsmeyer discloses “a sequence consisting essentially of BAX ART domain, wherein sequence of Bax comprises SEQ ID NO.: 3, wherein Bax is human, mouse and is capable of decreasing apoptosis.”

Applicants respectfully traverse this rejection.

The present claims are directed to polypeptides consisting of, or essentially of, a BAX ART domain. An ART domain is defined in the specification (see page 6, line 24 through page 7, line 2) as “a domain of a BAX protein which, in the absence of a death signal, interacts with the transmembrane domain of BAX, thereby preventing the insertion of BAX into the mitochondria.” Thus, in order to be considered a BAX ART domain, a polypeptide must be capable of interacting *in its entirety* with the transmembrane domain of the BAX polypeptide.

Korsmeyer does not disclose a polypeptide consisting essentially of, or consisting of, a BAX ART domain. Rather, Korsmeyer discloses the naturally occurring full-length BAX polypeptide. While containing a BAX ART domain, the BAX polypeptide taught by Korsmeyer includes an additional 170 amino acids and the polypeptide does not interact with the BAX transmembrane domain or prevent insertion of BAX into the mitochondria, and consequently, this polypeptide does not consist essentially of, or consist of, the ART domain of the claimed invention. Thus, because Korsmeyer does not

teach the claimed polypeptide, applicants respectfully request that this rejection be withdrawn.

## CONCLUSION

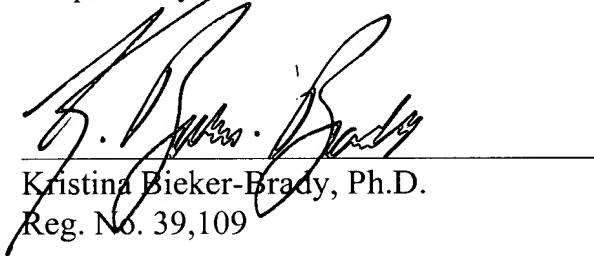
Applicants submit that the claims are now in condition for allowance and such action is respectfully requested.

Applicants further note that the Form PTO-1449 that was submitted with an Information Disclosure Statement filed on June 6, 2001 has not been initialed and returned, and hereby request that it be initialed and returned with the next Office action.

Enclosed is a Petition to extend the period for replying to the Office action for one month, to and including May 15, 2003, and a check in payment of the required extension fee.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



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50013.011002 Reply to Office Action Mailed on January 15, 2003



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